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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,638	07/15/2002	Martin Matthew Matzuk	MTN-029US	5196

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EXAMINER	
QIAN, CELINE X	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,638	MATZUK ET AL.	
	Examiner	Art Unit	
	Celine X. Qian Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7,8,10-13 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,8,10-13 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-4, 7, 8, 10-13 and 25 are pending in the application.

This Office Action is in response to the Amendment filed on 4/8/05.

Response to Amendment

Acknowledgement is made of Applicant's submission of the replacement drawings 1, 6 and amendment of the specification in compliance of the sequence rule.

The objection to the specification has been withdrawn in light of Applicant's submission of the abstract and amendment of the specification.

The rejection of claims 1-3, 7, 8, 10-13 and 25 under 35 U.S.C. 112 2nd paragraph has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 1-4, 7, 8, 10-13 and 25 under 35 U.S.C. 112 1st paragraph is maintained for reasons set forth of the record mailed on 10/6/05 and further discussed below.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 7, 8. 10-13 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to this rejection, Applicants argue that the amended claims have sufficient written description support in the specification. Applicants assert that the disclosure provides a detailed description of how to identify and characterize the claimed GDF-9 molecules from variety of sources including mammalian and avian genomic DNA libraries or synthesized from a variety of known and sequenced GDF-9 genes. Applicants further assert that the specification teaches methods for preparing expression vectors which comprise the identified regulatory elements and methods for transfecting cells with such vectors, and provides working examples which demonstrate how the claimed molecules can be tested for regulating expression of genes as claimed. Applicants thus conclude that the written description requirement is satisfied.

The above arguments have been fully considered but deemed unpersuasive. The detailed reasons for this rejection were discussed in the previous office action. The amended claims are drawn to an isolated polynucleotide comprising a GDF-9 regulatory element comprising a portion of a nonhuman GDF-9 gene capable of regulating expression of an operably linked gene in oocytes or testis, wherein the portion is selected from the group consisting of the first 10kb of DNA immediately 5' of the transcription start site or a portion thereof, the first 3.3 kilobases of DNA immediately 5' of the transcription start site or a portion thereof, an intron, and the first 1kb of DNA immediately 3' of the transcription termination site or a portion thereof, and wherein the portion is greater than 261 nucleotide in length. This claimed genus of polynucleotides encompasses potentially a large number of DNA fragments of various sizes and from different animal species, wherein said DNA fragments can be either 5' (within 10kb or 3.3kb) or 3' (within 1 kb) of the GDF-9 gene, or from the intron of said gene. The specification only discloses a 10 kb fragment immediately 5' from the transcription start site of the mouse

GDF-9 gene that directs transcription of GFP in mouse ovary, and a 3.3 kb fragment immediately 5' from the transcription start site of the mouse GDF-9 gene that directs transcription of GFP in mouse ovary and testis. The specification does not describe a regulatory element of any size in any other non-human animal that can direct testis or ovary specific gene transcription. The specification also fails describe any fragments larger than 261 bp isolated from either 5' or 3' of the mouse GDF-9 gene or in any intron of the GDF-9 gene that can direct ovary or testis specific transcription. In analyzing whether the written description requirement is met, it is first determined whether a representative number of species have been described by their complete structure. Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. The instant specification only discloses one nucleic acid sequence capable of promoting expression in ovary and testis, the mouse 3.3 kb fragment immediately 5' to the GDF-9 gene, one fragment that directs expression in ovary, but not testis, the mouse 10 kb fragment immediately 5' to the GDF-9 gene. In view of the large genus that is claimed, this hardly represents a representative number of species. Further, the specification fails to teach what is the critical/essential element that the claimed polynucleotide must have for its function of regulating expression in oocyte or testis. Applicants are reminded that the written description requirement requires that the specification to describe a representative number of species of the claimed invention by their complete structure or other identifying characteristics. The disclosure of methods for identifying the claimed invention is not itself a description of the structure of the claimed invention. The disclosure of the method of testing whether the claimed invention has regulatory function in oocyte or testis does not constitute the description of the structure of the claimed invention either. As such, the

specification fails to describe the claimed invention in such a way to convey one skilled in the art that Applicants had possession of the invention at the time the application is filed.

The claims also recites "an isolated regulatory element capable of promoting expression of an operably linked gene in oocytes or testis, comprising the first 3.3 kb of DNA immediately 5' of the transcription start site of a GDF-9 gene, or portions thereof, wherein the regulatory element is greater than 261 nucleotide in length." This also encompasses a large number of polynucleotide of various sizes and from different animal species, wherein said DNA fragments comprises different sequences. Based on the limited disclosure of the specification as discussed above, it is unclear what is the necessary element within the mouse 3.3kb 5' sequence that would function as oocyte/testis specific regulatory element. As such, the specification fails to describe a representative number of claimed polynucleotide by their complete structure or other identifying characteristics. Since the specification fails to describe of the claimed polynucleotide in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, it also fails to describe the vector and cell comprising said polynucleotide. Therefore, the written description requirement is not satisfied,

The claims also recites "an isolated regulatory element capable of promoting expression of an operably linked gene in oocytes from the 3.3 kb to 10 kb of DNA immediately 5' of the transcription start site of a GDF-9 gene, wherein the regulatory element downregulates expression of a gene in testis." This also encompasses a large number of polynucleotides from different animal species, wherein the sequences are different from each other. The specification only discloses that there is a possible testis transcription repressor within the region of 3.3 kb to

10 kb 5' of the mouse GDF-9 gene. The specification fails to disclose testis transcription repressor in the same region in any other species of the non-human animal. The specification also fails to describe the size or sequence of such repressor. As such, the structural functional relationship of such repressor is missing. Therefore, the written description requirement is not satisfied, and this rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELIAN QIAN
PATENT EXAMINER